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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the Orthosphere® Spherical Implant.

Submitted By:	Wright Medical Technology, Inc.
Date:	January 29, 2003
Contact Person:	Katie Logerot Regulatory Affairs Specialist
Proprietary Name:	Orthosphere® Spherical Implant
Common Name:	Ceramic Spherical Implant
Classification Name and Reference:	21 CFR 888.3770 Prosthesis, Wrist, Carpal trapezium – Class II 21 CFR 888.3730 Prosthesis, Toe, Hemi-, Phalangeal – Class II
Device Product Code and Panel Code:	Orthopedics/87/ KYI Orthopedics/87/KWD

DEVICE INFORMATION

A. INTENDED USE

The indications for use for the Orthosphere® Ceramic Spherical Implant are substantially equivalent to the indications for use previously submitted under Ceramic Spherical CMC.

The Orthosphere® Ceramic Spherical Implant is indicated for use in cases of isolated carpometacarpal (CMC) or $4^{th}/5^{th}$ tarsometatarsal (TMT) joint involvement from either degenerative or post-traumatic arthritis presenting:

- Decreased motion
- X-ray evidence of arthritic changes and/or subluxation of the carpometacarpal or tarsometatarsal joints

headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 **901.867.9971** phone **www.wmt.com**
international subsidiaries
011.32.2.378.3905 Belgium **905.826.1600** Canada **011.33.1.45.13.24.40** France **011.49.4161.745130** Germany
011.39.0250.678.227 Italy **011.81.3.3538.0474** Japan **011.44.1483.721.404** UK

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- Localized pain and palpable crepitation during circumduction movement with axial compression of the involved thumb ("grind test")
- Associated unstable, stiff, or painful distal joints
- Decreased pinch and grip strength
- Degenerative joint disease of the midfoot associated with gout or pseudogout

Only sizes 9mm-12mm are indicated for use in the tarsometatarsal (TMT) joints. Sizes 9mm-14mm are indicated for use in the carpometacarpal (CMC) joints.

The Orthosphere® Ceramic Spherical Implant is for single use only.

The extended indication for use of the Orthosphere® Ceramic Spherical Implant in the tarsometatarsal joint is substantially equivalent to the indications for use of the Swanson Titanium Great Toe previously submitted and cleared. Both implants articulate on bone and act as a spacer to preserve joint space and allow appropriate capsuloligamentous reconstruction in the foot.

B. DEVICE DESCRIPTION

The device description of the Orthosphere® Ceramic Spherical Implant is identical to the device description of the Ceramic Spherical CMC Implant.

The design features of the Orthosphere® Ceramic Spherical Implant previously submitted and cleared are summarized below:

- Manufactured from zirconia ceramic
- Highly polished surface finish
- Acts as a spacer to preserve joint relationship and allow appropriate capsuloligamentous reconstruction to correct deformities
- Will rest in a spherical cavity and articulate directly on bone

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features of the Orthosphere® Ceramic Spherical Implant are identical to the Ceramic Spherical CMC Implant. The material, intended use and type of interface of the Orthosphere® Ceramic Spherical Implant are substantially equivalent to the Ceramic Spherical CMC Implant and the Swanson Titanium Great Toe Implant. The safety and effectiveness of using this implant for interpositional arthroplasty of the foot are adequately supported by the substantial equivalence information and materials data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2003

Ms. Katie Logerot
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K030319
Trade/Device Name: ORTHOSPHERE® Ceramic Spherical Implant
Regulation Numbers: 21 CFR 888.3730
Regulation Names: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Codes: KWD
Dated: August 28, 2003
Received: August 29, 2003

Dear Ms. Logerot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030319

ORTHOSPHERE® Ceramic Spherical Implant

INDICATIONS STATEMENT

The Orthosphere® Ceramic Spherical Implant is indicated for use in cases of isolated carpometacarpal (CMC) or 4th/5th tarsometatarsal (TMT) joint involvement from either degenerative or post-traumatic arthritis presenting:

- Decreased motion
- X-ray evidence of arthritic changes and/or subluxation of the carpometacarpal or tarsometatarsal joints
- Localized pain and palpable crepitation during circumduction movement with axial compression of the involved thumb ("grind test")
- Associated unstable, stiff or painful distal joints
- Decreased pinch and grip strength
- Degenerative joint disease of the midfoot associated with gout or pseudogout

Only sizes 9mm-12mm are indicated for use in the 4th/5th tarsometatarsal joints. Sizes 9mm-14mm are indicated for use in the carpometacarpal (CMC) joints.

The Orthosphere® Ceramic Spherical Implant is for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

Prescription Use ✓
(Per21 CFR 801.109)

Over-The Counter Use ____
(Optional Format 1-2-96)

for Mark A. Milhan DR
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030319

headquarters
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